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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,289	10/15/2003	Ivan Osorio	011738.00141	8969

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EXAMINER

STOKLOSA, JOSEPH A

ART UNIT	PAPER NUMBER
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3762

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/687,289	Applicant(s) OSORIO ET AL.	
	Examiner JOSEPH STOKLOSA	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 16-37 and 39-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-37 and 39-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/24/2009, 2/25/2009</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 17-18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.
2. Claims 17 and 18 are substantially duplicate claims, where the only difference is claim 17 recites the "retrieving and storing data **by** the external component" and claim 18 recites "retrieving and storing data **via** the external component." Examiner suggest Applicant cancel at least one of these claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 3762

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-13, 16-19, 21-32, 35-37, 39-51 rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst (US 2002/0013612) in view of Terry et al. (US 5,154,172).

4. Whitehurst discloses a system and method for treating mood or anxiety disorders, which is a nervous system disorder, by stimulating the brain using an implantable system control unit (SCU), electrodes and a pulse generator (e.g. ABSTRACT).

5. Whitehurst discloses open and closed loop operation, with automatic switching between the two modes (e.g. paragraphs 84, 92, and 90), but fails to explicitly teach the implantable component continues to support the feature provided by the external unit if it does not receive a signal from the external unit during a first period of time, until a second period of time and operate in open-loop mode, when it detects that the first external component is no longer in communication it automatically switches to a second therapy mode. Terry teaches that it is known to operate in both open and closed loop modes, after a period of time determining if external unit is in communication, then continuing in a first operation mode, until it determines the external component is no longer in communication (the external programmer did not communicate) and switch to a second operation mode when the external programmer is re-coupled as set forth in Fig. 3A and Col. 10, line 3-53 for providing the predictable results of ensuring proper and efficient therapy is delivered either through external programming of stimulation

Art Unit: 3762

parameters or through internal unit algorithms and also providing power management. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Whitehurst with the implantable component continues to support the feature provided by the external unit if it does not receive a signal from the external unit during a first period of time, until a second period of time and operate in open-loop mode, when it detects that the first external component is no longer in communication it automatically switches to a second therapy mode, and operate in both open and closed loop modes, after a period of time determining if external unit is in communication, then continuing in a first operation mode, until it determines the external component is no longer in communication (the external programmer did not communicate) and switch to a second operation mode when the external programmer is re-coupled as taught by Terry, since such a modification would provide the predictable results of ensuring proper and efficient therapy is delivered either through external programming of stimulation parameters or through internal unit algorithms and also providing power management.

6. With regard to claims 2-3 and 5, Examiner considers the MDS 194 to be the programmer in direct communication with the SCU and the CPS to be a programmer in indirect communication with the SCU (e.g. paragraph 82), and HHP 190 to function as a relay module, and the third treatment mode to be administration of drug stimulation.

7. With regard to claim 6, Examiner considers Whitehurst to necessarily disclose a memory configured to store data, because Whitehurst discloses selective telemetry of

Art Unit: 3762

data which necessitates a memory for storage of the date prior to telemetry (e.g. paragraph 90).

8. With regard to claim 24-25, Whitehurst discloses a hybrid system with internal and external components/systems (e.g. seen generally in Fig. 6).

9. With regard to claim 7 and 26-27, Whitehurst discloses sensors/sensing means for detection of symptoms of the disorder that indicate need for treatment (e.g. paragraph 28).

10. With regard to claim 8, Whitehurst discloses a second communications channel (e.g. communications channel 246).

11. With regard to claim 9-10, 12, 23, and 32, Whitehurst discloses an additional module or external component in the form of a clinician programming device, CPS 192, which is capable of communicating with the SCU via the HPP 190. The CPS 192 can also support an additional treatment therapy, such as administration of drug therapy.

12. With regard to claim 16 and 37, Examiner considers Whitehurst to disclose basic loop recording and enhanced loop recording since the data is recorded and when there is communication between the implant and external programmer the recorded data is enhanced loop recording since there is external feedback.

13. With regard to claim 17-18, Whitehurst implant sensing/recording and storage and retrieval by the external programmer (e.g. paragraph 88).

14. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst in view of Terry as applied above.

Art Unit: 3762

15. Whitehurst in view of Terry disclose the invention as claimed but fails to explicitly teach the second therapy being configured to support an alarm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Whitehurst in view of Terry with an alarm in the second therapy mode since such a modification would provide the predictable results of ensuring patient safety by serving as notification of impending condition/disorder that requires immediate attention so that the patient may seek appropriate care.

16. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst in view of Terry as applied above, and further in view of Haller et al. (US 2002/0013613).

17. Whitehurst in view of Terry disclose the invention as claimed but fail to explicitly teach sensing patient location. Haller teaches that it is known to sense patient location through GPS as set forth in Fig. 6C and paragraph 88 for providing the predictable results of monitoring the patient location and providing the patient location to EMS in the event of a severe medical condition/event. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Whitehurst in view of Terry with sensing patient location through GPS since such a modification would provide the predictable results of monitoring the patient location and providing the patient location to EMS in the event of a severe medical condition/event.

Response to Arguments

18. Applicant's arguments with respect to claims 1-13, 16-37, 39-51 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on 571-272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Niketa I. Patel/
Supervisory Patent Examiner, Art Unit 3762

Joseph Stoklosa
Examiner
Art Unit 3762

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2/14/2011